JUN - 6 2012

K121507 P1/2

ATRICURE Cryo Module System 510(k) SUMMARY

General Information

Date Compiled	May 8, 2012
Classification	Class II
Product Code	GEH, 21 CFR 878.4350
Trade Name	AtriCure *Cryo Module System (ACM, Cryo1, and cryoICE)*
Manufacturer	AtriCure, Inc 6217 Centre Park Drive West Chester, OH 45069 (513) 755-4100 (513) 644-1354 (fax)
Contact	James L. Lucky VP of Quality Systems and Regulatory Affairs

Indications for Use

The AtriCure Cryo Module System is intended for use in the cryosurgical treatment of cardiac arrhythmias. The System consists of the AtriCure Cryo Module (ACM)—a non-sterile, reusable device—used with the Cryo1 cryo-ablation probe—a sterile, single use device—and/or the cryoICE cryo-ablation probe—a sterile, single use device.

Cleared Device

The device proposed for modification in this submission is the AtriCure *Cryo Module System (ACM, Cryo1, and cryoICE)* (K112072).

Device Description

The AtriCure Cryo Module (ACM) unit is a non-sterile reusable electro-mechanical and pneumatic cryogenic surgical system that delivers a cryogenic energy source, namely Nitrous Oxide, to an AtriCure cryo-ablation probe to create lines of ablation through cardiac tissue for the treatment of cardiac arrhythmias. The AtriCure cryo-ablation probe (Cryo1 or cryoICE) is a sterile, single use, cryosurgical device to be used in conjunction with the AtriCure Cryo Module or frigitronics CCS-200 Cardiac Cryosurgical System [K811390] to freeze target tissue, blocking the electrical conduction pathways by creating an inflammatory response or cryonecrosis.

Materials

All materials used in the manufacture of the AtriCure Cryo Module System are safe and suitable for their intended use and suitable for their use with pressurized nitrous oxide. The ACM is not intended for patient contact. Testing has been previously conducted in accordance with ISO 10993-1 to ensure biocompatibility of all appropriate materials in the AtriCure cryo-ablation probes (Cryo1 and cryoICE).

Testing

Appropriate product testing was conducted to evaluate conformance to product specification and substantial equivalence to predicate devices. Transit testing, design verification and validation, software validation, etc. were completed to show that the ACM is substantially equivalent and in conformance international standards and device specifications. The standards and FDA Guidance used to determine substantial equivalence include, but are not limited to:

- UL 60601-1: Medical Electrical Equipment, Part 1: General Requirements for Safety. (2006)
- EN 60601-1: Medical Electrical Equipment – Part 1: General Requirements for Safety (1998) +A1 +A2, 2nd Edition
- IEC 60601-1-2: Collateral Standard- Electromagnetic Compatibility – Req. & Tests (2007)
- EN 55011: Industrial, scientific and medical (ISM) radio-frequency Equipment. Electromagnetic disturbance characteristics. Limits and methods of measurement. (2007)
- ISTA Procedure 3A: Packaged – Product for Parcel Delivery System Shipment 70kg (150 lb) or Less; (2008)
- ASTM F882-84: Standard Performance and Safety Specification for Cryosurgical Medical Instrument's (2002)
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (Issued May 11, 2005)

Summary of Substantial Equivalence

The modified AtriCure *Cryo Module* System proposed in this submission is considered substantially equivalent to the AtriCure Cryo Module System cleared via K112072. The indications for use, basic overall function, and materials used are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Atricure, Inc.
c/o Mr. Mark Job
Reviewer
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 53313

JUN - 6 2012

Re: K121507
Trade Name: Atricure Cryo Module System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II (two)
Product Codes: GEH
Dated: May 18, 2012
Received: May 21, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121507

Device Name: AtriCure *Cryo Module System (ACM, Cryo1, and cryoICE)*

Indications For Use:

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Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121507